Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IL2006/000006

International filing date: 01 January 2006 (01.01.2006)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/639,987
Filing date: 30 December 2004 (30.12.2004)

Date of receipt at the International Bureau: 01 September 2006 (01.09.2006)

Remark: Priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b)

PCT/IL2006/000006
13 AUG 2006

PA 1482869

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 28, 2006

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***60/639,987***
FILING DATE: ***December 30, 2004***

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS ***US60/639,987***

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

L. Edelen

L. EDELEN
Certifying Officer

Attorney Docket No. P-7569-USP

United States Provisional Patent Application For:

DEVICE, SYSTEM AND METHOD FOR OPERATING DIGITAL FLUOROSCOPE

Inventors

David Lavenda
6 Pearl Dr.
Wesley Hills, NY 10952

Ronald Lavenda
39 Brownlea Rd.
Framingham, MA 01701

Michal Devir
1 Hamezach St.
Kfar Vitkin, Israel

David Arlinsky
11 Hamat Hamim St.
Atlit, Israel

Gershon Goldenberg
11 Dgania St.
Carcur, Israel

necessitating specialized electrical power sources and, for "mobile" units, heavy and bulky arrays of batteries. Even so called "portable" or "mini" units typically weigh over 100 kg and are portable only by the virtue of special carts that facilitate limited movement.

Furthermore, most x-ray systems currently in use for both fluoroscopy and radiography utilize high intensity x-radiation, which high intensity is dictated, in large part, by the relatively low gain or limited degree of light amplification provided by conventional image intensification techniques. The high radiation intensities employed in these systems also require the use of x-ray tubes employing large area focal spots since otherwise the high beam currents would generate too much heat and lead to rapid deterioration of the tube anode (unless cooled by a bulky cooling mechanism). X-ray tubes employing large area focal spots necessitate operation at long source to image distances in order to maintain satisfactory image resolution or definition.

Recent advances in digital x-ray technology have afforded a viable way to product an ultra-lightweight x-ray/fluoroscope that is both highly mobile and low in x-ray intensity, so that it can be operated by non-specialized personnel, and without the need for specialized protection. However, we believe that merely scaling down the existing solution is not sufficient to fulfill the needs for "on site" radiological examinations. This is because portable units in use today are operated by highly trained radiation technicians, skilled in both the operation of the equipment and the safety restrictions dictated by its dissemination of radiation. The PixRay invention described in this document is intended for use by non-specialized personnel.

Patentable innovations make the portable fluoroscope both practical and cost effective to a huge segment of the point of care population. Some of the innovations are detailed in this document.

Potential Applications

The PixRay micro C-Arm has applications in multiple disciplines including, but not limited to the following:

- Medicine – including veterinary medicine (equine), sports medicine, military medicine, emergency medicine, and geriatric medicine (nursing home applications).
- Security – including in-site package inspection and screening.
- Industry – including inspection of welds and the structural integrity of objects including aviation components, marine vessels, buildings, pipes, electronic components and assemblies, etc.

System Characteristics

The Micro C-Arm provides the following functionality:

- Small enough to be portable and self-contained. *Portable* means able to be carried, deployed, and operated by non-special personnel. One of the benefits of the micro C-Arm is that it can eliminate the need to have specialized personnel present to carry out fluoroscopic examinations. *Self-contained* means that the unit must be operational without the need for additional elements.
- Powerful enough to penetrate examination objects and to provide a detailed moving picture of the subject.

The C-Arm system specifications for the medical/orthopedic application are as follows:

- Field of View = ≥ 6"
- Thickness of subject = 15"
- Voltage – 90-110 kVP
- Current = 0.2 mA
- Weight ≤ 15 lbs.

System Description

The PixRay micro C-Arm is a portable, self-contained fluoroscopic x-ray device. The device shown schematically in the following figure:

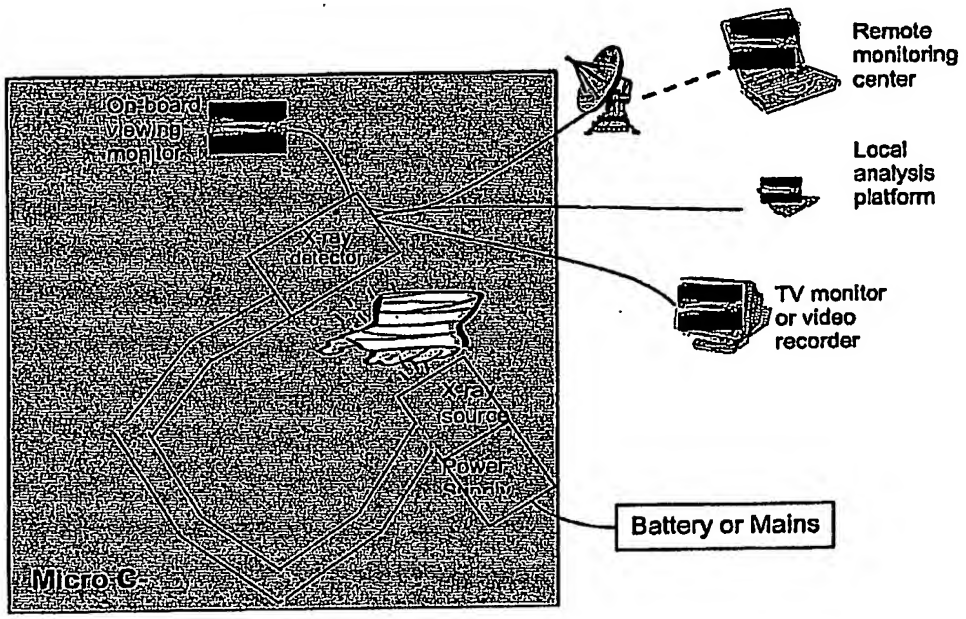


Figure 1 – Micro C-Arm

Micro C-Arm Components

The micro C-Arm is made up of the following components:

- X-ray source assembly
- X-ray target assembly
- Power Supply / X-ray tube driver
- C-Arm mechanical assembly
- Fluoroscope control system
- C-Arm stand
- Monitoring and diagnostic apparatus

A schematic diagram of the system is shown in the following figure:

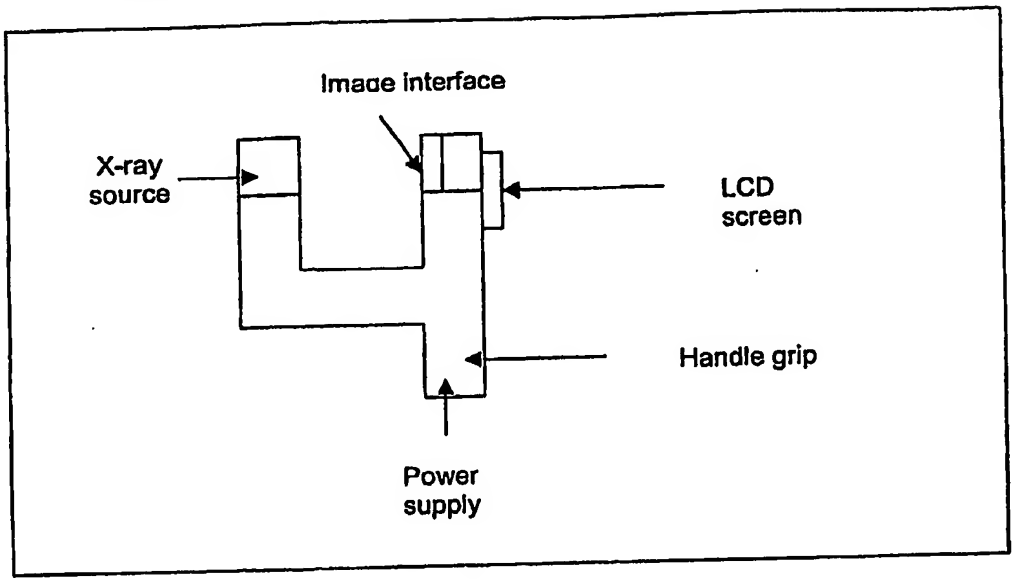
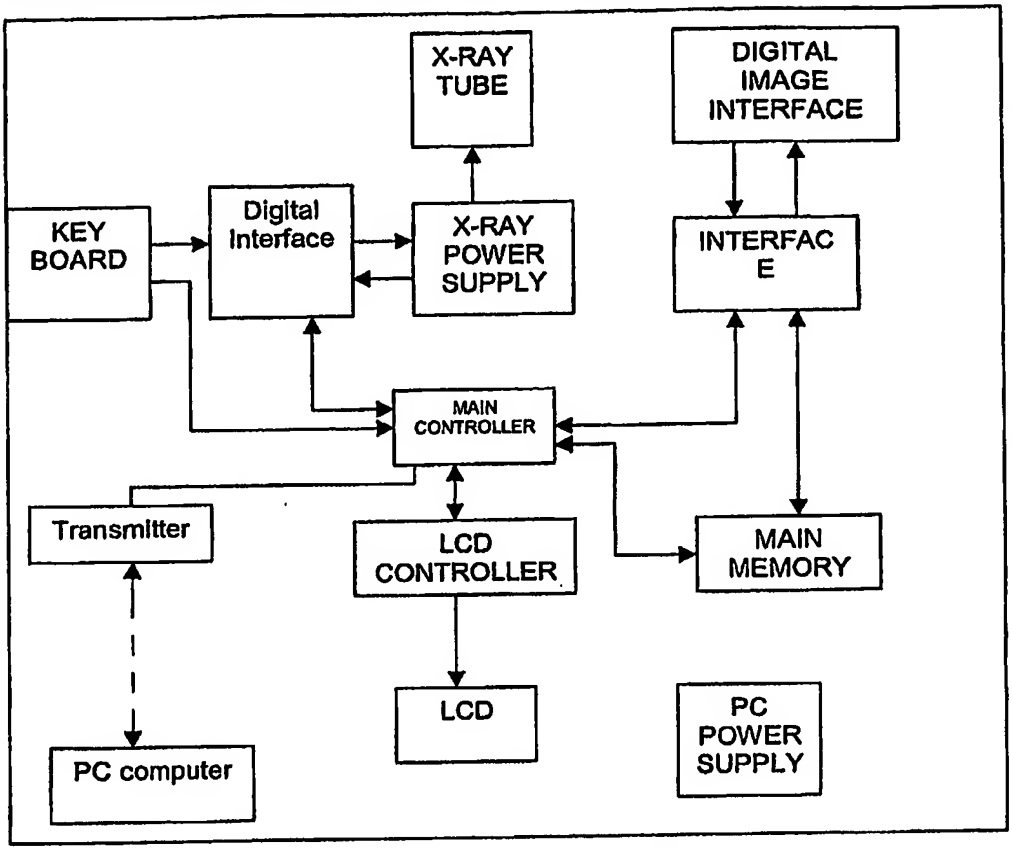


Figure 2 - Schematic Diagram of the PixRay micro C-Arm

A block diagram of the system is shown in the following figure:



The system contains the following components. The main components are described in depth in later sections.

- **X-ray tube** – component that generates the radiation need to create the fluoroscopic image.
- **Regulated power supply** – miniature power supply that uses rational techniques to generate high voltage at low currents to drive the x-ray tube using a micro-controller. The voltage and current are selected via a keypad mounted on the C-Arm assembly.
- **Digital image interface** – a surface sensitive to X-ray radiation and is capable of converting x-ray energy into electrical signals.

- **Interface** – converts the electrical currents generated on the digital image interface to voltages according to addresses on the surface matrix (which are scanned to produce a picture.)
- **Controller** – manages the entire system and regulates the flow of information from the system memory to the output device, e.g. LCD screen or PC (for image processing or display).
- **Display** (e.g. LCD) – shows system menus related to ongoing system operation and displays the object under observation when the system is active (i.e. the fluoroscopic image).

The main components of the system are described in the following sections.

X-ray Source

The X-ray source consists of the following parts:

- **X-ray tube** – a small x-ray tube; because of the unique method by which the tube is powered, no active cooling mechanism necessary.
- **Power supply** – the power supply uses a unique strategy of powering the x-ray tube. The power supply rapidly switches the voltage on and off so that the tube does not overheat, and therefore does not require cooling. There are several advantages to this approach; they are:
  - o X-ray tube assembly is smaller/lighter and therefore, more portable.
  - o Power supply is able to provide higher power while being much more electrically efficient
  - o Power supply is be able to achieve high power values without requiring cooling[2].

  The power supply is a key part of the invention; it will be covered as a separate component, below.

X-ray Target

The X-ray target is located at one end of the C-Arm, in the traditional fashion of conventional C-Arms. The components contained in the target include convert X-ray radiation into signals that can be processed into a "meaningful" picture. Several technologies are available for the target for example amorphous silicon panels and integrated image intensifier/CCD camera plates. The ability to incorporate a meaningful size target (8" viewing) while keeping the weight low is a key factor in the PixRay micro C-Arm device. These set of components are able to process the x-ray data at video rates (≥ 30 fps) in order to show a continuous picture.

[2] This has been one of the difficult parts of building a truly portable C-Arm; you either have to sacrifice portability to achieve the necessary power, or you have to sacrifice the power requirements, and then severely reduce the utility of the device.)

Power Supply / X-Ray Tube Driver

The power supply is one of the key components in the micro C-Arm. One of the biggest problems in reducing the size of a portable C-Arm is directly related to the power supply. In order to achieve the power necessary to drive an x-ray tube for "real-world applications," power supplies have been large and unwieldy. The power that they generate heats the x-ray tube to a point where the tube has to be cooled, typically in an oil bath. In fact, the power supply itself has to be oil cooled as well. This is one of the factors that has caused fluoroscopes to be big (and heavy). Another problem is that when the x-ray tube overheats, it generates additional radiation. This radiation has be handled by adding lead insulation (and hence even more weight) to the tube assembly and by requiring the subject (and operator) to wear lead protection.

One inventor[3] has developed a handheld x-ray fluoroscopic device, but he overcame the heat problem by severely limiting the power of the device. As such, the device is appropriate only for x-raying human hands and feet. This invention did not address the heat/radiation/power supply; it restricts operating levels to those that do not meet the requirements of most x-ray fluoroscopy applications. The approach taken by the PixRay micro C-Arm is novel and non-trivial in that it is able to generate significant power (110 kV at 0.2mA) without requiring cooling or shielding mechanisms.

The Micro C-Arm overcomes the power supply/radiation/overheating problem by using a novel approach to power supply design. In what we call the "alternator approach," the power supply switches on and off rapidly, in much the same way, an automobile alternator works. The advantages to this approach are several-fold:

- Power supply is small and contained
- Power supply does not need oil-cooling
- X-ray tube does not require oil-cooling
- X-ray tube does not require additional lead insulation
- Power requirements are less than those of a standard power supply and therefore the device can be run longer on batteries
- No lead protection is needed

The power supply is able to provide the following (continuous) operating values:

- Voltages up to 110 kVP
- Current up to 0.2 mA

[3] US Patent 4,856,036 "Method for Production of Fluoroscopic and Radiographic X-ray Images and Hand-held Diagnostic Apparatus Incorporating the Same," Malcolm et al, 1989, and US Patent 4,979,198 – same title and authors as above, 1990.

C-Arm Mechanical Assembly

The C-Arm is so called because of the representative shape of the assembly (which resembles the letter "C"). X-ray C-Arms have been manufactured for years and by a variety of vendors. Typically, the C-Arm is mounted on a stationary assembly that facilitates manipulation in order to view a wide range of body parts. These assemblies are by nature stationary and are typically housed in a specially-designed radiology center.

Some vendors[4] have manufactured "portable" or "mini" C-Arms. These are devices that are mounted on movable carts. They typically weigh hundreds of pounds and require a truck to move them from place to place.

Other vendors[5] manufacture portable C-Arms powered by radiologically-active isotopes, but these devices are unwieldy and are impractical for use in the field. One vendor markets a portable x-ray tube-powered C-Arm, but this arm is too small to be useful for anything by the smallest appendages[6].

In general, the C-Arm serves several purposes; they are as follows:

- Houses the X-ray source assembly
- Houses the X-ray target assembly
- Properly positions the source and target assemblies
- Houses the monitoring and diagnostic components (CCD camera, LCD viewing monitor, output ports for external monitoring and diagnostic equipment, etc.)
- Provides for the positioning and manipulation of the X-ray device; this includes at least one of the following:
    - Hand grips for holding and positioning the device (manually)
    - Mounting bracket for connecting the C-Arm to a stationary platform or mobile apparatus that manipulates and maintains the position of the C-Arm during operation.
- Provides the controls for the X-ray device[7]
- Providesa safe environment for radiological examination (for the subject and for the operator)

The basic C-Arm assembly is a mechanical assembly that facilitates the functionality described in the aforementioned list.

[4] GE Lunar, OEC, Xitec, Toshiba and others
[5] Lixi Corp. for example.
[6] Xitec Corp.

[7] The control may optional be operational via remote control (depending on the application).

There are several innovations built into the PixRay micro C-Arm mechanical assembly; they are as follows:

- Onboard video monitor (via LCD screen for example) built onto the C-Arm itself
- Innovative use of materials to achieve extremely lightweight assembly, so that device is usable by non-specialized personnel.

Fluoroscope Control System

The fluoroscope control system consists of a control panel and the associated control mechanism needed to operate the C-Arm, as well as required safety features mandated by law.

The control panel for the C-Arm includes one or more of the following:

- Switches embedded within the C-Arm assembly
- Control panel connected to the C-Arm via cable assembly
- Control panel connected to the C-Arm via wireless connection (i.e. a wireless remote control)
- Foot switch for turning the device on or off.
- Foot-operated controller (e.g. mouse or joystick) for positioning and controlling the fluoroscope. The operator is able to select from system menus using the foot-operated controller.

The control panel incorporates the following functionality:

- System Power On/Off switch
- Fluoroscope On/Off switch (or foot switch, or timer that shuts the system off automatically)
- Voltage Selector
- Current Selector
- Alternatively, the voltage and current selector can be combined into one "exposure setting"

The control system also contains necessary safety features dictated for devices that generate x-rays. Some important functions supported by the control system include the following:

- Automatic shutoff switch that turns the system off in case the tube or circuitry overheats.
- Fuse assembly
- Voltage limiter
- Current limiter

PixRay Micro C-Arm Support Stand

The PixRay micro C-Arm incorporates a unique and novel support stand that allows the operator to use the fluoroscope without having to hold it in place. The C-Arm be operated using one hand or alternatively using no hands (operating the device using the foot controller, or possibly a head up display), so that the operator can view the subject in three-dimensions while the hands free for other tasks. The stand supports the following motion:

- **Linear motion** – this allows an operator to traverse or scan an object. For example, a doctor can take a continuous x-ray of a patient's forearm. Furthermore, the system automatically builds a composite photo from different frames of the fluoroscopic movie made while the PixRay micro C-Arm scans the object.
- **Rotational motion** permits complete 360° rotation along two axes (simultaneously). This allows the operator to develop a 3-dimensional view of the subject at hand. Imaging software supplied with the PixRay device presents a 3-d view of the object under observation for detailed analysis. This is a unique feature of a miniature device that is typically provided for in much larger devices, using cumbersome and unwieldy mechanisms that do not scale down to the dimensions of the micro C-Arm. A schematic representation of the C-Arm stand's motion is shown in the following figure.

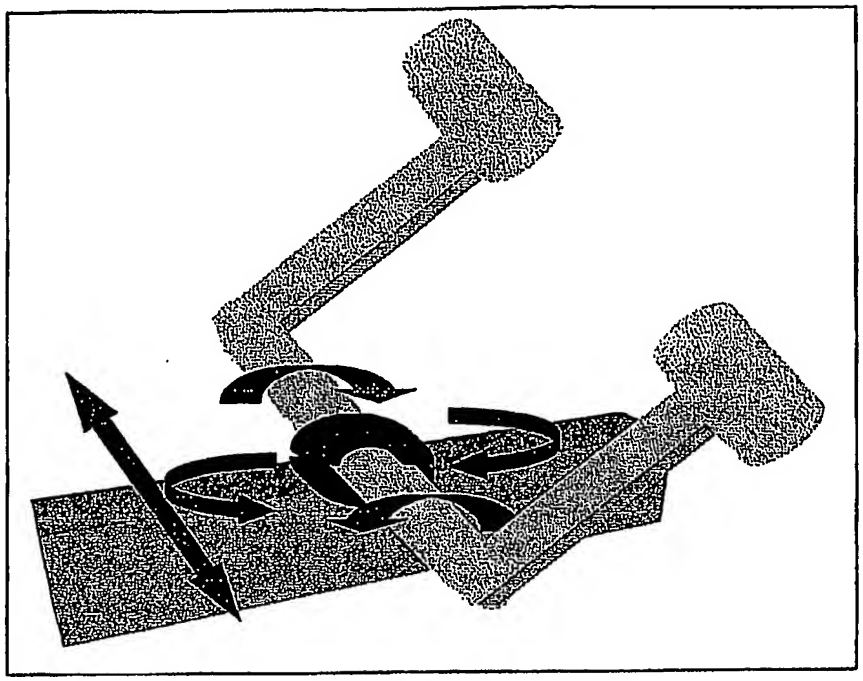


Figure 3 – C-Arm stand motion

The C-Arm can of course, disengage from the C-Arm stand so that it can be used in a free-standing position by the operator.

Monitoring and Diagnostic Apparatus

The output of the micro C-Arm is an x-ray movie that can be monitored and analyzed by one or more of the following methods:

- On-board viewing monitor (e.g. LCD monitor similar to those used on typical video cameras)
- External output to video monitor
- External output to video recorder
- External output to computer for further processing

The external image presentation/analysis apparatus is connected to the C-Arm either using standard cables (e.g. coax) or is transmitted via a wireless connection. The system uses current wireless technology (e.g. Bluetooth, Wi-Fi, etc.) and will likely evolve as the product evolves.

The information can be passed to an external computer, so that the following information can be made available to the operator:

- Bone densiometric measurements of subject
- Three-dimensional analysis of x-ray images
- Image enhancements of x-ray movie
- Photo montage, e.g. superimposing a conventional movie/photograph on to the fluoroscopic picture, so that it is easy to locate a distinctive marking seen on the fluoroscopic image on the object under observation. This is a novel innovation in the PixRay device.
- Composite photographs built automatically from several movie frames These pictures are built automatically by the device once the scan is complete. The operator stops the C-Arm operation and then the device automatically builds and displays a static picture made up of multiple segments of the scan. The final "product" appears as a complete x-ray photo of the entire scanned section. The device incorporates the intelligence to correctly connect the different pictures so that the resultant picture appears as a single photograph, showing a much larger viewing area than offered by the x-ray target cross section.
- Other processing of x-ray images
- Image compression for sending to a remote operator/analyst for further analysis.

Some of these image processing capabilities are novel innovations, heretofore not available.

Another novel function is the ability to offer a predefined set of radiographic procedures, so that the operator does not have to manually x-ray and then perform the specific analysis. Rather, the operator chooses a menu item that configures the C-Arm, takes the x-ray, and post-processes the image to provide the necessary output. An example of this is the device's ability to automatically perform densiometric analyses, without having to do have the procedure being done in steps.

Summary of Innovations

The PixRay micro C-Arm incorporates a number of innovations; these innovations include novelty in product design, as well as in application (i.e. the use of portable fluoroscopy for diagnostic purposes). The following list summarizes some of the main innovations included in the PixRay micro C-Arm product.

- The fluoroscope is the first to be truly portable and to produce the power necessary to perform x-ray examinations beyond human hands and feet. The innovation here may not be in the "portability" but rather in the utility of the device. While one other device was patented as portable[8], design constraints restricted its intended use to limited applications. Our breakthrough involves how we power the x-ray tube (which is the next innovation.)
- The micro C-Arm uses a novel approach to powering the x-ray tube. While other devices use a conventional power supply, the PixRay mirco C-Arm adopts the "alternator approach" which, like an automobile alternator, rapidly turns the tube on and off. This approach presents at least two advantages – the tube does not produce as much heat (and therefore requires less insulation and lead protection), and the power required by the system is reduced (thus facilitating better use of batteries to power the system). While one inventor[9] has patented an "X-ray Tube Power Supply" that basically switches the tube on and off, the PixRay micro C-Arm uses a novel approach that allows the tube to generate the level of power necessary to view large bone human appendages with a high degree of resolution and sensitivity. Other methods are limited in terms of what they can generate and are not relevant for the applications detailed in this document.
    - The aforementioned circuit prevents x-ray tube heating and therefore eliminates the need for an oil-cooled x-ray tube. This is the first fluoroscope to achieve this accomplishment. The implications are reduced weight and complexity.
    - The aforementioned circuit also eliminates the need for a cooling system for the power supply. While others[10] were able to achieve an air-cooled power supply in a portable fluoroscope, nobody has been able to achieve it for the necessary power levels that are required for the intended applications. The limitation cited is necessarily a significant one, in that the aforementioned inventor could not reach the energies needed to build a fluoroscopic device

[8] US Patent 4,856,036 "Method for Production of Fluoroscopic and Radiographic X-ray Images and Hand-held Diagnostic Apparatus Incorporating the Same," Malcolm et al, 1989 and US Patent 4,979,198 – same title and authors as above, 1990
[9] US Patent 6,496,563 - "X-Ray Tube Driver," Bacon, 2002.
[10] Ibid, Malcolm et al.

as described in this document. The prior art is necessarily limited to low energies (and therefore is precluded from the applications described in this document).
    - The power levels achieved by the PixRay micro C-Arm facilitate a larger source/target distance. The distances listed on patents[11] for portable devices are too small for all but the most limited applications (human hands and feet). Again, these limitations are necessarily significant due to limitations in the methods described in the prior art.
    - Use of the aforementioned circuitry limits the scattered radiation and therefore reduces the amount of radiation to which the subject and operator are exposed. The PixRay micro C-Arm requires no Lead aprons for the intended applications.
- The C-Arm incorporates adjustable arms that allow the x-raying of items of varying depth; this facilitates the x-raying of different size body parts with the most convenient configuration. No other portable system allows you to adjust the throat depth in order to conform to the requirements of a specific subject. The system allows motion that increases/decreases the distance between the X-ray tube and the target, as well as changes the "throat depth" of the C-Arm to get around large object. The PixRay micro C-Arm can open and close like a clam around an object that represents an obstacle to x-raying the subject.
- The C-Arm controllable via a remote controller (e.g. joystick or mouse). Using the controller (which may be mounted directly on the arm, may be remote controlled, or may be operated by foot), the operator can position the imaging device.
    - The ability to control the PixRay micro C-Arm using a foot is useful in that an operator, for example a surgeon, is able to use both hands simultaneously and operate the imaging device with their foot. This is especially important to surgeons using the fluoroscope to assist them during surgery (e.g. minimally invasive surgery).
- The fluoroscope embeds a high quality on-board video monitoring and diagnostic tool (via LCD or other screen) on the C-Arm itself. Until now, the operator either looked directly into the image intensifier on the C-Arm or the signal was sent to an external device for processing. This is the first time the analysis can be displayed directly on the device itself. Other innovations regarding this presentation option:
    - Touch screen LCD monitor on arm with C-Arm commands shown directly on the monitor.
- The product provides a novel use of lightweight materials to achieve extreme portability so that device can be used by "ordinary personnel."
- This is the first handheld, portable device to provide image analysis as part of the system output. Some of the image analysis technology may be licensed from other vendors. Examples of image analysis include, but are

[11] Ibid., Malcolm et al.

not limited to the following: bone densiometry, image enhancement, compression for transmitting the images wirelessly to a remote terminal.

- The PixRay C-Arm provides the ability to display both a visible photograph superimposed over the X-ray view of the subject. In this way, the viewer can see where on the subject the area of interest is located. For example, if an operator is looking for a broken bone, they can see a photo of the arm superimposed over the x-ray, so they can see where on the body the break has occurred.
- Additionally, scales (both linear and angular) can be viewed on the C-Arm display that lets the operator measure distances or angles between multiple points of interest on the subject, directly on the screen. The scales can also be saved with the photo so that it can be printed out or used for later analysis.
- A "back off" function exists that lets an operator X-ray a subject, then move the C-Arm out of the way. A subsequent command returns the C-Arm to precisely the position and orientation that existed prior to the "back off" command. This is an important and novel feature for surgeons performing operations, where they want to be able to remove the C-Arm momentarily (e.g. so that they can position themselves better vis a vis the patient). Once they want to view the subject again, the C-Arm can be returned to its original position without having to do any manual manipulation. This feature may be controlled via the foot controller so that the surgeon can keep both hands available for the operation.

Additional Applications

In addition to the medical application described herein, PixRay foresees a potential for expanding into the following fields of concentration.:

- **Medical** –medical applications other than those described in this document
- **Security** –inspecting suspicious packages or suitcases, without the need to move the package to a stationary x-ray inspection system.
- **Industrial** – on-site structure inspection (e.g. aviation components, construction elements like pipes, supports, etc., marine components, and large immobile structures)

CLAIMS

What is claimed is:

1. A device comprising elements described in the specification and drawings.

2. A system comprising elements described in the specification and drawings.

3. A method comprising processes described in the specification and drawings.